
CHAPTER 4

RISK EVALUATIONS DURING THE FEASIBILITY STUDY

4.1 INTRODUCTION

The following are FS activities, which during development, should involve EPA risk assessor input. Continuous involvement of the EPA risk assessor during the FS has the benefit of: 1) supporting the development of remedial action objectives (RAOs) and PRGs, and 2) supporting comparison of risks associated with various remedial alternatives. For these reasons, EPA risk assessor involvement in FS preparation and review is strongly encouraged.

The purpose of the FS is to evaluate waste management remedial alternatives. The *National Oil and Hazardous Substance Pollution Contingency Plan (NCP)* (EPA 1990c) specifies that a detailed analysis be performed that involves nine criteria. The NCP specifies that for screening of remedial alternatives, the long-term and short-term aspects of three criteria - effectiveness, implementability, and cost - should be used to guide the development and screening of remedial alternatives. Consideration of effectiveness involves evaluating the long-term and short-term human health risks. Long-term risks associated with a remedial alternative are those risks that will remain after the remedy is complete; short-term risks associated with a remedial alternative are those risks that occur during implementation of the remedial alternative.

Evaluating long-term risks ideally includes an assessment of the risks associated with treatment of residuals and untreated wastes for a treatment-based remedy, or an evaluation of the remedy's ability to provide protectiveness over time for a containment-based remedy. For short-term human health risks associated with a remedial alternative, a risk assessor may need to evaluate the risks that occur during implementation of the remedial alternative (e.g., risks associated with emissions from an onsite

air stripper). Because some remedies may take many years to complete, some "short-term" risks may actually occur over a period of many years. Populations that may be exposed to chemicals during remedy implementation include people who live and work in the vicinity of the site.

The NCP also requires that RAOs and remediation goals be developed. These serve as objectives and goals that can be used to identify and assess remedial alternatives at Superfund sites. The remainder of this chapter defines and discusses RAOs and remediation goals.

4.1.1 REMEDIAL ACTION OBJECTIVES

As discussed in the NCP, RAOs describe, in general terms, what any remedial action needs to accomplish in order to be protective of human health and the environment. They are typically narrative statements that specify the contaminants and environmental media of concern, the potential exposure pathways to be addressed by remedial actions, the exposed populations and environmental receptors to be protected, and the acceptable contaminant concentrations or concentration ranges (remediation goals) in each environmental medium.

4.1.2 REMEDIATION GOALS

Remediation goals are a subset of the RAOs. They provide the acceptable contaminant concentrations in each medium for remedial actions to meet.

EPA explained in the preamble to the final NCP that remediation goals are based on ARARs unless ARARs are not available or are not protective. ARARs do not always exist for all chemicals and all environmental media.

SELECTION OF REMEDIATION GOALS

The NCP [EPA 1990c; Section 300.430(e)(2)(I)] states that the selection of remediation goals should consider the following:

“...remediation goals shall establish acceptable exposure levels that are protective of human health and the environment and shall be developed considering the following...

ARARs under Federal environmental or State environmental or facility siting laws, if available, and the following factors:

1. For systemic toxicants, acceptable exposure levels shall represent concentration levels to which the human population, including sensitive subgroups, may be exposed without adverse effect during a lifetime or part of a lifetime, incorporating an adequate margin of safety;
2. For known or suspected carcinogens, acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between 10^{-4} and 10^{-6} using information on the relationship between dose and response. The 10^{-6} risk level shall be used as the point of departure for determining remediation goals for alternatives when ARARs are not available or are not sufficiently protective because of the presence of multiple contaminants at a site or multiple pathways of exposure;
3. Factors related to technical limitations such as detection/quantification limits for contaminants;
4. Factors related to uncertainty; and
5. Other pertinent information.”

Therefore, according to the NCP, there are two major sources for the acceptable exposure levels used for remediation goals: a) concentrations found in Federal and State ARARs and, if these are not available or not protective, (b) risk-based concentrations that are determined to be protective of human health and the environment. These risk-

based concentrations are calculated using, at a minimum, the criteria cited in numbers 1 and 2 in the Remediation Goals highlight box. Other factors mentioned in the highlight box [i.e., limits of detection (number 3), uncertainty (number 4), and background concentration levels (number 5)] are also considered.

Risk-based concentrations may need to be developed for all chemicals even if ARARs are available to ensure that these ARARs are protective of human health and the environment.

ARAR-Based Remediation Goals. Potential chemical-specific ARARs include concentration limits set by Federal environmental regulations such as Maximum Contaminant Levels (MCLs) established under the Safe Drinking Water Act (SDWA), ambient water quality criteria established under the Clean Water Act (CWA), and State regulations (e.g., State drinking water laws). Action-specific and location-specific ARARs must also be complied with according to the NCP.

Risk-Based Remediation Goals. In general, remediation goals based on risk-based calculations are determined using cancer or non-cancer toxicity values with specific exposure assumptions. For chemicals with carcinogenic effects, the NCP has described the development of remediation goals, as a practical matter, as a two-step process [EPA 1990c, Section 300.430(e)(2)(I)(D)]. A concentration equivalent to a lifetime cancer risk of 1×10^{-6} is first established as a point of departure. Then, other factors are taken into account to determine where within the acceptable range the remediation goals for a given contaminant at a specific site will be established.

The NCP discusses a generally acceptable risk range of 1×10^{-4} to 1×10^{-6} . EPA has further clarified the extent of the acceptable risk range by stating that the upper boundary is not a discrete line at 1×10^{-4} . Risks slightly greater than 1×10^{-4} may be considered to be acceptable (i.e., protective) if justified based on site-specific conditions, including any uncertainties about the nature and extent of contamination and associated risks. [See *Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions* (EPA 1991d)]

For non-cancer effects, the NCP states that an acceptable exposure level must be defined (using reliable toxicity information such as EPA's RfD). According to EPA guidance, (RAGS Part A, EPA 1989c), generally, if the Hazard Index (HI) (Intake/RfD) is above 1 (i.e., the site exposure is estimated to be above the RfD) there may be a concern for potential non-cancer effects [see *Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions* (EPA 1991d)]. Therefore, in calculating remediation goals at a site to protect for non-cancer effects, remediation goals are generally set at a Hazard Index at or below 1.

4.1.3 PRELIMINARY REMEDIATION GOALS

As discussed in the NCP, final remediation goals are not determined until a final remedy for the site is selected in the ROD. However, PRGs for a site are established as early in the RI/FS process as possible during project scoping (see Chapter 2). These initial PRGs can then be modified as necessary during the FS, based on site-specific information from the baseline risk assessment. The PRGs will then be used to establish the goals to be met by the remedial alternatives in the FS. The PRGs also guide the development of the Proposed Plan for remedial action and the selection of remediation levels in the Record of Decision.

Risk-based PRGs (non-ARARs) may be modified within the acceptable risk range during the remedy selection process based on a balancing of the major trade-offs among the alternatives as well as the public and Agency comments on the Proposed Plan (RAGS Part B). Such balancing among alternatives and consideration of community and State acceptance will establish the specific level of protection the remedy will achieve (i.e., the final remediation levels).

The dialogue begun during Scoping between the EPA risk assessor and the EPA RPM should continue during the FS and beyond to ensure that risk assessment information is used appropriately in the risk management decision process.

The primary guidance on development of the FS is available in "*Guidance for Conducting Remedial Investigations and Feasibility Studies Under*

CERCLA (EPA 1988). RAGS Part B (EPA 1991a) also presents guidance for the role of risk assessment in the FS. The EPA RPM should follow appropriate National and regional guidance.

4.2 DEVELOP REMEDIAL ACTION OBJECTIVES

The risk assessor should be involved in the preparation or review of the following:

- A narrative description of the Medium, Exposure Point and Exposure Routes, and chemicals exceeding the risk range
- A narrative identifying the remedial action objectives for prevention of exposure and restoration of each contaminated Medium (e.g., restoring groundwater to a potable water source)
- A format such as Example Table 1 in Exhibit 4-1 may be a useful approach to present these data for each Medium.

4.3 DEVELOP REMEDIATION GOALS

The risk assessor should be involved in the preparation or review of a short narrative or tables which provide the goals of the remediation. First, all values considered as PRGs should be identified. Then the PRGs selected for each chemical to be used in the FS should be presented.

4.3.1 IDENTIFY VALUES CONSIDERED AS PRELIMINARY REMEDIATION GOALS

- Identify ARAR-based PRGs and associated risks/hazards.
- If ARAR-based PRGs are not protective, calculate risk-based PRGs using EPA methods.
- Identify other values to consider as PRGs [e.g., background, detection limits, Procedure Quantitation Limits (PQLs)].
- A format such as Example Table 2 in Exhibit 4-

1 may be a useful approach to present these values, for each Medium and Receptor Population combination.

4.3.2 SELECT PRELIMINARY REMEDIATION GOALS

- Select PRG(s) for each chemical from among the values considered (e.g., risk-based for cancer and non-cancer, ARAR-based, other), modifying values as appropriate. Note that the PRG should be ARAR-based unless there is no ARAR available or the ARAR is not protective.
- Provide the rationale for the selected PRG. Include the source of the value.
- A format such as Example Table 3 in Exhibit 4-1 may be a useful approach to present these values for each Medium and Receptor Population combination.

4.4 SUMMARIZE RISKS AND HAZARDS ASSOCIATED WITH PRELIMINARY REMEDIATION GOALS

The risk assessor should be involved in the preparation or review of a short narrative or tables which summarize the risks and hazards associated with the PRGs.

- Identify the chemical of concern, maximum concentration, PRG, basis of PRG, and calculated risks and hazards associated with the PRG for each Medium and Receptor Population.
- Summarize the total risk and total hazard among all chemicals for each Medium and Receptor Population combination.
- A format such as Example Table 3 in Exhibit 4-1 may be a useful approach to present these values for each Medium and Receptor Population combination.

4.5 EVALUATE REMEDIAL TECHNOLOGIES AND ALTERNATIVES FOR RISK

CONSIDERATIONS

The risk assessor may provide input in the process of evaluating remedial technologies and alternatives for risk considerations beginning in the development and screening stage of the FS and extending into the detailed analysis stage. The major goal for the risk evaluation during these steps is to provide the FS team and the EPA RPM with specific long-term and short-term human health risk information to consider when identifying and screening technologies and alternatives and performing detailed analysis of alternatives.

The long-term human health risks associated with a remedial technology or alternative are those risks that will remain after the remedy is complete (i.e., residual risks). The risk issues to be considered may include an assessment of the risks associated with treatment residuals, untreated wastes, or contained wastes.

The short-term human health risks associated with a remedial technology or alternative are those risks that occur during implementation of the technology or alternative, which may occur over a period of years. Populations to be considered include people who live and work in the vicinity of the site and workers involved in site remediation.

4.5.1 IDENTIFICATION AND SCREENING OF TECHNOLOGIES AND ALTERNATIVES

The risk assessor may contribute to the identification and screening of technologies and alternatives and focus on evaluating associated short-term and long-term human health risks to ensure that they meet RAOs and PRGs. The goal of the risk assessor is to assist in identifying, and eliminating from further consideration, technologies and/or alternatives with clearly unacceptable risks. This evaluation is typically

qualitative, based on simplifying assumptions and professional judgement rather than detailed analysis. The risk assessor's evaluation is associated with the consideration of effectiveness, one of three criteria specified by the NCP. (Implementability and cost are the other two criteria evaluated at this screening stage, but they do not typically involve risk assessor

participation.)

4.5.2 DETAILED ANALYSIS OF ALTERNATIVES

The overall objective of the risk assessor's role in the detailed analysis of alternatives is to support the preparation and evaluation of the risk information needed for RPMs to select a remedial alternative for a site. The risk assessor contributes to the analysis of three of the nine criteria specified by the NCP:

- Overall Protection of Human Health and the Environment
- Long-term Effectiveness and Permanence
- Short-term Effectiveness.

The detailed analysis of short-term and long-term risks may be qualitative or quantitative depending on the "perceived risk" associated with the alternative based on both professional judgement and community concerns. The risk analysis follows the same general steps as the baseline risk assessment; however, the steps will typically not be conducted in the same level of detail for the FS.

The detailed analysis of short-term risks includes the following components for each alternative:

- Evaluate short-term exposure.
- Evaluate short-term toxicity.
- Characterize short-term risks to the community (including people who live or work on or near the site).
- Characterize short-term risks to remediation workers (a qualitative assessment may be appropriate if the risks to remediation workers are addressed adequately in the site-specific Health and Safety Plan).

The detailed analysis of long-term risks includes the following components for each alternative.

- Evaluate residual risk.
- Evaluate protectiveness over time.